UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,042	03/13/2006	Shubha Anand	BJS-620-406	8188

23117 7590 02/14/2008

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
KUDLA, JOSEPH S	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
02/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,042	ANAND ET AL.	
	Examiner	Art Unit	
	Joseph S. Kudla	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *11-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Preliminary Amendment

1. Applicants' Amendment filed January 3, 2008 is acknowledged. The amended Claims, amended Specification, Information Disclosure Sheet and Abstract have been placed in the file. Claims 33-51 have been cancelled. Claims 1-32 remain under consideration.

Election/Restrictions

2. Applicant's December 9, 2007 correspondence elects Group I, without traverse, which encompasses claims 1-10. Applicant further elected breast cancer as the disease. Claims 10-32 are withdrawn from consideration as being drawn to non-elected subject matter. See 37 CFR 1.142(b). Accordingly, the subject matter now under consideration is drawn to claims 1-9.

Priority

3. This application is the US national phase of international application PCT/GB03/002862, filed July 3, 2003. Priority is acknowledged.

4. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on July 3, 2003. It is noted, however, that applicant has not filed a certified copy of the PCT/GB2003/002862 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

5. The Information Disclosure Sheet (IDS) correspondence submitted by Applicant on February 10, 2005 is acknowledged. The references have been reviewed to the extent each is a proper citation on a U.S. Patent.

6. The listing of references in the Search Report is not considered to be a proper citation complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification Objections

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

7. The abstract discloses a "means for predicting" which constitutes legal phraseology.

Clarification is required.

Specification

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent

application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an

understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

8. The specification of a utility application should include the above sections in order. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading. Specifically, none of the section headings, nor disclosure of a cross-reference to priority or nor a disclosure of joint research agreements are present.

Appropriate action is required.

9. The year for the PCT application is incorrect in the amendment to the specification filed January 3, 2006. Specifically, the year is disclosed as PCT/GB203/002862. It is believed that Applicant intended the year to be PCT/GB03/002862.

Appropriate action is required.

Title

10. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: METHOD OF INCREASING THE EFFICACY OF A MITOTIC SPINDLE ASSEMBLY INHIBITOR WITH AN AURORA KINASE INHIBITOR.

Claim Objections

11. Claim 4 is objected for the following informalities: The second line of the claim begins with the number four. The Examiner believes that Applicant, while amending the current claim set and similar to amended claim 5, inadvertently did not strike the reference to claim 4.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 2 recites the limitations "said tumors," and "said agent."
There is insufficient antecedent basis for these limitations in the claim.

14. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Applicant claims "or a derivative." Because the instant specification does not provide written description of what structures are contemplated for such "derivative," the phrases lack adequate written description.

Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F. 3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a

precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish list or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant has failed to provide any written description of the "derivatives" in the instant specification, aside from the broad recitation of suitable alternatives of taxanes disclosed by Applicant in the instant specification on page 3, lines 29-33. Applicant has failed to provide disclosure indicating the functional characteristics of the "derivatives" when combined with an aurora kinase inhibitor. As such, it is not apparent that Applicant was actually in possession of, and intended to use within the context of the present invention, any derivatives of taxane, at the time the present invention was made.

Appropriate action is required.

15. Claims 1-13, 15, 19-21, 26 and 39-41are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for:

a) a method of treating *all* cancers in an individual comprising administering an Aurora kinase inhibitor and a mitotic spindle assembly inhibitor;

b) a method of treating *any* cancer in an individual comprising administering an Aurora kinase inhibitor and a mitotic spindle assembly inhibitor;

c) the administration of a taxane with an Aurora kinase inhibitor;

and

d) the administration of a chemical agent or an antibody molecule functioning as an Aurora kinase inhibitor with a taxane.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims without undue experimentation to treat *any* cancer in an individual comprising administering an Aurora kinase inhibitor and a mitotic spindle assembly inhibitor.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)*. A conclusion of lack of enablement means that, based on

the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The claimed invention relates to chemotherapy, and specifically to a method for inhibiting the proliferation of cancer cells (e.g., all cancers) and tumor growth using a mitotic spindle assembly inhibitor and an Aurora kinase inhibitor. Applicant has not provided sufficient evidence to support a claim set drawn to treating cancer outlined in

the instant claim set with the composition having an Aurora kinase inhibitor and amitotic spindle assembly inhibitor. The breadth of the claims exacerbates the complex nature of the subject matter to which the present claims are directed.

The nature of the invention and the state of the prior art

The instant claim set outlines an invention that treats *all* cancers in an individual comprising administering an Aurora kinase inhibitor and a mitotic spindle assembly inhibitor. The instant claim set additionally outlines that the Aurora kinase inhibitor can be a chemical agent or an antibody molecule.

While the state of the art is relatively high with regard to the treatment of specific cancer types, the state of the art with regard to treating cancer broadly is underdeveloped. In particular, there is no known anticancer agent that is effective against all cancer cell types. A reference by Cecil (Cecil Textbook of Medicine, 21st Edition (2000), Goldman & Bennett (Editors), W.B. Saunders Company (Publisher), Chapter 198, pages 1060-1074), clearly shows that for the various known cancer types, there is no one specific chemotherapeutic agent that is effective for all types of cancer (see page Table 198-5 at page 1065; Tables 198-6 and 198-7 at page 1066; Table 198-8 at page 1068; and Table 198-9 at page 1071).

In the instant case, it has been demonstrated in prior art by Anand et al. ("AURORA-A amplification overrides the mitotic spindle assembly checkpoint, inducing resistance to Taxol," 2003, Cancer Cell, Vol. 3 pages 51-62 and cited by Applicant) that over-expression of AURORA-A overrides the checkpoint mechanism that monitors

mitotic spindle assembly (Abstract), therefore, effectively subverting the mechanism of action of a mitotic spindle assembly inhibitor. However, the prior art is silent on the ability an Aurora kinase inhibitor, whether the inhibitor is an antibody molecule or a chemical agent, to increase the efficacy of the Taxol, thus treating the cancer/tumor.

The level of predictability in the art

The instant claimed invention is highly unpredictable. Due to the general unpredictability in the pharmaceutical art and the lack of prior art showing the effects of the Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition in *an individual* treating *any cancer*, Applicant would need to show evidence of the likelihood that the Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition would have the desired physiological response through examples or scholarly discussion showing the nexus between what is commonly known in the art and that which Applicant asserts is his invention. In this particular case, the Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition is required to be assessed for physiological activity by *in vivo* screening to determine if the Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition exhibits the desired pharmacological activity of treating any cancer.*No studies were conducted with an Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition in* ***any*** *subject having* ***any*** *cancer.* The prior art is silent and the discussion by Applicant to the feasibility of an Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition to treat any cancer leads one of ordinary skill in the art to believe the invention is speculation.

Therefore, one cannot predict the ability of the composition to elicit *any* pharmacological response, because the results were neither exemplified in Applicants' specification nor shown in the prior art. In addition, one of ordinary skill in the art cannot predict if an Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition is effective for treating any cancer. In the only example provided on pages 21-24 in the instant specification, Applicant chose to transfect HeLa cells with a known gene construct with Taxol and compare the results against HeLa cells with only Taxol. This exemplifies that Aurora-A overexpression induces a striking increase in resistance to paclitaxel-induced apoptosis (page 23, lines 11-13), which appears to be opposite of the invention which Applicant is claiming. The parameters assessed in the study are not adequate to support *any* of Applicants' instant claims, and one cannot predict with any certainty if an Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition is effective for treating *any cancer*.

Applicant is reminded of the decision *Genentech Inc. vs. NovaNordisk* which states, " [A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit 1997).

The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting the claimed therapeutic regimen for the treatment of cancer. *In re Fisher, 427 F. 2d, 833, 166 USPQ 18 (CCPA 1970)*, indicates that the more unpredictable an area is, the more specific

enablement is necessary in order to satisfy the statute. Hence, one of skill in the art is unable to fully predict the ability of an Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition to treat *any cancer*.

The amount of direction provided by the inventor and the existence of working examples

The instant specification does not provide adequate guidance, which would allow the skilled artisan to extrapolate from the disclosure and examples provided, to practice the claimed methods commensurate in the scope with the instant claims. Applicant provides *no* guidance using an Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition to treat an individual with any cancer as specified in instant claim 1, *no* administration of a taxane with an Aurora kinase inhibitor and *no* guidance demonstrating the administration of a chemical agent or an antibody molecule functioning as an Aurora kinase inhibitor with a taxane. Adequate enablement requires more than a mere statement that a compound treats a given condition.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention (*In re Wright, 999 F. 2d 1557, 1562; 27 USPQ 2d 1510, 1514 (Fed. Cir. 1993)*). The specification lacks sufficient disclosure to support applicant's claims of a method for treating *any cancer* with an Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition. There is not seen sufficient

working examples or data from references in the prior art providing a nexus between that which applicant asserts is supporting a method of treating cancer with an Aurora kinase inhibitor and mitotic spindle assembly inhibitor composition and the amount of disclosure Applicant has actually provided.

The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Based on the unpredictable nature of the invention, the state of the prior art and the breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation. The essential element towards the validation of a therapeutic modality capable of performing the mechanism of action is the ability to test the compound within *specific parameters* in advance of administration of a compound and, while maintaining experimental control, link those results with sampling time points. Once it can be documented that the compound of interest elicits a desired pharmacological response within experimental controls, the compound, for the sake of this forum, could generally be assumed to have that pharmacological activity.

Based on the unpredictable nature of the invention, the state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JK

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER 2/8/08